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72

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,664	12/21/2000	Ayoub Rashtchian	0942.3910003/RWE/BJD	7736
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STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			SITTON, JEHANNE SOUAYA	
			ART UNIT	PAPER NUMBER

1634

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/741,664

Applicant(s)

RASHTCHIAN ET AL.

Examiner

Jehanne S. Sitton

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3, 5-23, 26, 28, 29, 54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) 6, 7 and 10-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 8, 9, 26, 28, 29, 54, and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-3, 5-23, 26, 28, 29, 54, and 55 are pending in the instant application. Claims 6, 7, and 10-23 are withdrawn from consideration as being drawn to non elected species. Claims 1-3, 5, 8-9, 26, 28, 29, 54, and 55 are under consideration at this time. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejection not reiterated is hereby withdrawn in view of the amendments to the claims. The following rejections are either newly applied, as necessitated by amendment, or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow, where appropriate. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

3. Claims 1 and 54 are rejected under 35 USC 102(b) as being anticipated by Scalice.

Scalice teaches a composition containing Taq DNA polymerase (5 units/ml), Tris buffer with MgCl, Nonidet P-40 nonionic surfactant, Tween (claim 54), and an antibody (25nM) which binds to Taq polymerase (see col. 20, lines 19-24). Scalice teaches that the enzyme and antibody were incubated, and that subsequent to this, a *solution* comprising buffer and DNA template (nucleic acid molecule) was added to the composition containing polymerase and antibody. Thus Scalice teaches a method of synthesizing or amplifying a nucleic acid molecule comprising

Art Unit: 1634

contacting said nucleic acid molecule with a composition lacking nucleic acid molecules and comprising a mixture of reagents which are at least one thermostable DNA polymerase, at least one nonionic detergent, at least one buffer salt, and at least one antibody that binds to said thermostable enzyme, wherein said composition is not diluted prior to said contacting. In the instant case, the composition containing enzyme and polymerase is not diluted prior to contacting with the solution containing nucleic acid molecules. Accordingly, the teachings of Scalice anticipate the claimed invention.

Response to arguments

4. The response traverses the rejection. The response asserts that Scalice discloses a 2.5X concentrate, not reagents which are present at concentrations for performing methods without dilution. This argument has been thoroughly reviewed but was found unpersuasive as the claims do not recite “present at concentrations for performing methods without dilution”. The claims only recite that the composition is not diluted prior to “contacting”. This limitation is taught by Scalice. The fact that the composition is diluted in the contacting step does not distinguish the methods of Scalice from those of the instant claims. Additionally, the response’s arguments are confusing because for the methods to be functional, some dilution of the “composition lacking nucleic acid molecules” must take place because the composition does not contain any nucleic acid molecules. When the recited compositions are used for the claimed methods, nucleic acids would be required to be added in the form of primer(s) and/or nucleic acid template. Once added, the resulting composition for use in the method would be less concentrated, and thus diluted. For these reasons and the reasons already made of record, the rejection is maintained.

Claim Rejections - 35 USC § 103

5. Claims 1-2, 5, 8-9, 26, 28, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen (Olsen et al; WO 95/00664) in view of Sobol, and Gelfand (Gelfand et al; US Patent 5,618,703) and Scalice.

Olsen teaches methods of performing multiple PCR reactions using different primer pair and templates to identify primer pairs suitable for detection of Salmonella species in samples (see para bridging pages 2-3; page 7, first full para; page 14, last para). Olsen teaches that the PCR reactions contained 105 uL comprising template DNA, 50mMKCL, 2.5 mM MgCl₂ (instant claim 26), 10 mM Tris, 200uM each dNTP (instant claim 28), 0.5% Tween, and 2.5 units of Taq polymerase (23.8 U/ml). Olsen is silent with regard to the steps of making of the composition prior to template addition. Olsen does not teach a PCR reaction mix containing an antibody that binds to the thermostable enzyme.

However, Sobol discloses the use of master mixes of reagents while preparing multiple samples for PCR (see col. 17, lines 19-44), wherein the master mix includes PCR reagents, including polymerase, other than primers and template. Sobol exemplifies methods wherein the PCR master mix is aliquoted to different reaction tubes where the reagents are present at concentrations which are not diluted prior to the addition of nucleic acids. It is well known to those of skill in the art that a master mix is typically employed when performing multiple reactions in order to improve efficiency and consistency and to avoid pipetting error. For example, Gelfand teaches methods of performing multiple reverse transcription reactions wherein all reagents are added in a master mix containing a thermostable polymerase, such as Taq, a nonionic detergent, all 4 dNTPs, and a buffer salt where the reagents are present at

Art Unit: 1634

concentrations which are not diluted prior to the addition of nucleic acids (see cols 27, 28, 30 and 31). Gelfand specifically teaches a method wherein multiple samples were analyzed and “for consistency and to avoid pipetting errors” the mix was prepared as a master mix and aliquoted as 17 uL into different reaction tubes such that only a single uL of primer and 2 uL of template were added (see col. 31).

Scalice teaches that the use of an antibody specific for a thermostable DNA polymerase, such as Taq (cols 7-8), can be used to reduce or eliminate the formation of non specific products in PCR methods (see abstract). Scalice teaches that the enzyme and antibody were incubated, and that subsequent to this, a solution comprising DNA template was added to the composition containing polymerase and antibody.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the multiple PCR methods using different primers and template of Olsen with the use of a master mix containing all reagents necessary for the reaction except for primer and templates such that the methods could be performed requiring only contacting the PCR master mix with nucleic acid template and primers, as taught by Sobol and Gelfand, for the purpose of increasing the consistency and to reduce pipetting errors in the reactions of Olsen. The ordinary artisan would have been motivated to use a master mix as taught by Sobol and Gelfand because Sobol and Gelfand each exemplify the ease of use of a master mix composition when different multiple reactions require analysis using different templates and primers, and Gelfand specifically teaches that the use of such master mixes improves consistency and reduces pipetting errors. Further, the ordinary artisan would have been motivated to have prepared a master mix including all the reagents except for primers and

Art Unit: 1634

template in order to have possessed a single master mix composition that could be successfully employed with a variety of different templates and primers, requiring the addition of a relatively small amount of primer and template and thus could be used in any amplification reaction. In performing the improved methods of Olsen in view of Sobol and Gelfand, the ordinary artisan would have arrived at a master mix composition which would require the addition of as little as a uL of primer and 5 uL of DNA template. For a 105 uL volume total reaction volume, the concentration of Taq polymerase would be about 25 U/ml in the master mix. The recitation of “about 20 U/ml” in claim 9 has been broadly interpreted to encompass 25 U/ml.

It would have been further prima facie obvious to one of ordinary skill in the art at the time the invention was made to have improved the method of Olsen in view of Sobol and Gelfand with the use of an additional component, an antibody specific for Taq polymerase as taught by Scalice in the master mixture of Olsen in view of Sobol and Gelfand. The ordinary artisan would have been motivated to add an antibody specific for Taq polymerase to the PCR master mix of Olsen in view of Sobol and Gelfand for the purpose of reducing the formation of non specific PCR products in the methods of Olsen because Scalice teaches that such antibody can be used to reduce or eliminate the formation of non specific products in PCR methods. The ordinary artisan would have been motivated to add the antibody to the PCR master mixture of Olsen in view of Sobol and Gelfand for the purpose of providing all necessary reagents other than primer and template for use in any PCR reaction.

Art Unit: 1634

6. Claims 1-3, 5, 8, 26, 29, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soderlund in view of Sobol and Gelfand (Gelfand et al; US Patent 5,618,703) and Scalice.

Soderlund teaches DNA sequencing methods using primer extension analysis for routine determinations of point mutations and specific nucleotide variations in any DNA template. Soderlund teaches utilizing specific detection primers, whose identity is dependent on the variation to be detected (see page 3, para 20-23). Soderlund teaches that reactions mixtures can contain at least one dNTP and at least one ddNTP (see para 55-59). Soderlund exemplifies a 50 uL reaction mixture containing 2 units of Taq polymerase (40 U/ml), a dNTP, a ddNTP (.8 uM), 1.5 mM MgCl₂, and 0.1% Tween (para 0117). Soderlund is silent with regard to the steps of adding reagents to perform primer extension reactions. Soderlund does not teach a composition containing an antibody that binds to the thermostable polymerase.

However, Sobol discloses the use of master mixes of reagents while preparing multiple samples for PCR (see col. 17, lines 19-44), wherein the master mix includes PCR reagents, including polymerase, other than primers and template. Sobol exemplifies methods wherein the PCR master mix is aliquoted to different reaction tubes where the reagents are present at concentrations which are not diluted prior to the addition of nucleic acids. It is well known to those of skill in the art that a master mix is typically employed when performing multiple reactions in order to improve efficiency and consistency and to avoid pipetting error. For example, Gelfand teaches methods of performing multiple reverse transcription reactions wherein all reagents are added in a master mix containing a thermostable polymerase, such as Taq, a nonionic detergent, all 4 dNTPs, and a buffer salt where the reagents are present at

Art Unit: 1634

concentrations which are not diluted prior to the addition of nucleic acids (see cols 27, 28, 30 and 31). Gelfand specifically teaches a method wherein multiple samples were analyzed and “for consistency and to avoid pipetting errors” the mix was prepared as a master mix and aliquoted as 17 uL into different reaction tubes such that only a single uL of primer and 2 uL of template were added (see col. 31).

Scalice teaches that there is a need to eliminate the hybridization of primers to non target nucleic acids and the formation of primer dimmers (col. 2, lines 17-18). Scalice teaches the use of an antibody specific for a thermostable DNA polymerase, such as Taq (cols 7-8), can be used to reduce or eliminate the formation of non specific products in primer extension reactions such as PCR (see abstract). Scalice teaches that the enzyme and antibody were incubated, and that subsequent to this, a solution comprising DNA template was added to the composition containing polymerase and antibody.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the methods of detecting different nucleotide variations in different targets of Soderlund, using different detection primers, with the use of a master mix containing all reagents necessary for the reaction except for templates and primers where the reagents are present such that no dilution occurs before contacting the master mixture with template and primer for the purpose of increasing the consistency and to reduce pipetting errors, as taught by Sobol and Gelfand, in the sequencing methods of Soderlund. The ordinary artisan would have been motivated to use a master mix as taught by Sobol and Gelfand because Sobol and Gelfand each exemplify the ease of use of a master mix composition when different reactions require analysis using different templates and primers, and Gelfand specifically teaches

Art Unit: 1634

that the use of such master mixes can improve consistency and reduce pipetting errors. Further, the ordinary artisan would have been motivated to have prepared a master mix including all the reagents except for primer and template in order to have possessed a single master mix composition that could be successfully employed with a variety of different templates and primers, requiring the addition of a relatively small amount of primer and template and thus could be used to sequence a large number of different nucleotide variations.

It would have been further *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have improved the method of Soderlund in view of Sobol and Gelfand with the use of an additional component, an antibody specific for Taq polymerase as taught by Scalice in the master mixture of Soderlund in view of Sobol and Gelfand. The ordinary artisan would have been motivated to add an antibody specific for Taq polymerase to the master mix of Soderlund in view of Sobol and Gelfand for the purpose of reducing the formation of non specific hybridization to non target nucleic acids in the methods of Soderlund because Scalice teaches that such antibody can be used to reduce or eliminate the formation of non specific products. The ordinary artisan would have been motivated to add the antibody to the master mixture of Soderlund in view of Sobol and Gelfand for the purpose of providing all necessary reagents other than primer and template for use in any primer extension reaction.

Art Unit: 1634

7. Claims 1-2, 5, 8-9, 26, 28, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnes in view of Hoeltke (Hoeltke et al; US Patent 5,814,502) and further in view of Sobol and Gelfand and Scalice.

Barnes teaches compositions for nucleic acid amplification comprising, for example, Klentaql, which is exonuclease free, or Taq, a salt buffer which contains magnesium (3.5 mM) and 250 μ M dNTPs (page 2217, col. 1, para 2). Barnes teaches that the compositions were used to amplify long nucleic acids (claim 33) larger than 8 kb (claims 37-39). Barnes is silent with regard to the order of steps of adding reagents for nucleic acid amplification. Barnes does not teach the compositions comprising a nonionic detergent, however Hoeltke teaches that nonionic detergents such as Triton X-100, Tween, Brij-35, and NP40 stabilize polymerases such as Taq (see col. 2, lines 45-54). Additionally, Gelfand teaches that detergents such as Tween-20 and Nonidet P-40 are present in enzyme dilution buffers and teaches reaction mixtures should be employed where they are preferably present at a final concentration of between 0.01-.1% (col. 19, lines 50-55). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the reaction mixture of Barnes to include a non ionic detergent for the purpose of stabilizing the reaction mixture of Barnes, as taught by Hoeltke. Further, it would have been prima facie obvious to one of ordinary skill in the art to include the use of a non ionic detergent in the composition of Barnes because Gelfand teaches that such are present in enzyme dilution buffers.

Barnes in view of Hoeltke does not specifically teach a composition for use in the method that doesn't contain nucleic acid molecules. Barnes in view of Hoeltke does not teach a composition containing an antibody with binds to the thermostable polymerase.

Sobol discloses the use of master mixes of reagents while preparing multiple samples for PCR (see col. 17, lines 19-44), wherein the master mix includes PCR reagents, including polymerase, other than primers and template. Sobol exemplifies methods wherein the PCR master mix is aliquoted to different reaction tubes where the reagents are present at concentrations which are not diluted prior to the addition of nucleic acids. It is well known to those of skill in the art that a master mix is typically employed when performing multiple reactions in order to improve efficiency and consistency and to avoid pipetting error. For example, Gelfand teaches methods of performing multiple reverse transcription reactions wherein all reagents are added in a master mix containing a thermostable polymerase, such as Taq, a nonionic detergent, all 4 dNTPs, and a buffer salt where the reagents are present at concentrations which are not diluted prior to the addition of nucleic acids (see cols 27, 28, 30 and 31). Gelfand specifically teaches a method wherein multiple samples were analyzed and “for consistency and to avoid pipetting errors” the mix was prepared as a master mix and aliquoted as 17 uL into different reaction tubes such that only a single uL of primer and 2 uL of template were added (see col. 31).

Scalice teaches that the use of an antibody specific for a thermostable DNA polymerase, including Taq (cols 7-8), can be used to reduce or eliminate the formation of non specific products in PCR methods (see abstract). Scalice teaches that the enzyme and antibody were incubated, and that subsequent to this, a solution comprising DNA template was added to the composition containing polymerase and antibody.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the methods of amplification of different targets of

Art Unit: 1634

Barnes in view of Hoeltke with the use of a master mix containing all reagents necessary for the reaction except for templates and primers such that the methods could be performed requiring only contacting the PCR master mix with nucleic acid template and primers, as taught by Sobol and Gelfand, for the purpose of increasing the consistency and to reduce pipetting errors in the reactions of Barnes in view of Hoeltke. The ordinary artisan would have been motivated to use a master mix as taught by Sobol and Gelfand because Sobol and Gelfand each exemplify the ease of use of a master mix composition when different multiple reactions require analysis using different templates and primers, and Gelfand specifically teaches that the use of such master mixes can improve consistency and reduce pipetting errors. Further, the ordinary artisan would have been motivated to have prepared a master mix including all the reagents except for primer and template in order to have possessed a single master mix composition that could be successfully employed with a variety of different templates and primers, requiring the addition of a relatively small amount of primer and template and thus could be used in to amplify an long nucleic acid target.

It would have been further prima facie obvious to one of ordinary skill in the art at the time the invention was made to have improved the method of Barnes in view of Hoeltke and further in view of Sobol and Gelfand with the use of an additional component, an antibody specific for the thermostable polymerases, as taught by Scalice in the master mixture of Barnes in view of Hoeltke and further in view of Sobol and Gelfand. The ordinary artisan would have been motivated to add an antibody specific for the thermostable polymerases to the PCR master mix of Barnes in view of Hoeltke and further in view of Sobol and Gelfand for the purpose of reducing the formation of non specific PCR products in the method of Barnes in view of Hoeltke

Art Unit: 1634

because Scalice teaches that such antibody can be used to reduce or eliminate the formation of non specific products in PCR methods. The ordinary artisan would have been motivated to add the antibody to the PCR master mixture of Barnes in view of Hoeltke and further in view of Sobol and Gelfand for the purpose of providing all necessary reagents other than primer and template for use in any PCR reaction.

Response to Arguments

8. Applicant's arguments directed to rejections under 35 USC 103(a), regarding references that teach compositions that contain nucleic acids, and the traversal on the basis that the skilled artisan reading these references "would be led in a direction divergent from the path that was taken by applicant", as well as arguments that such references teach away from the claimed invention, have been thoroughly reviewed but were found unpersuasive. These arguments are addressed with regard to newly applied rejections set forth above. Firstly, it is noted that rejections under 35 USC 103 directed to such references were not set forth *solely* based on the teachings of such references. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Secondly, in response to applicant's argument that 'the federal circuit held that 'references that teach away cannot serve to create a prima facie case of obviousness'" citing *In re Gurley* (Fed. Cir. 1994), it is noted that the MPEP, chapter 2123 states, "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred

Art Unit: 1634

embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). In the instant rejections, Olsen and Barnes are silent with regard to order of steps needed to arrive at the specific compositions containing nucleic acid molecules. There is no teaching "away" that the compositions are required to be made in any specific way. With regard to Soderlund, Soderlund actually teaches that the primer can be hybridized to the target and that a selected nucleoside triphosphate or a mixture of such can then be added. As exemplified by the teachings of Gelfand, the practice of pre-annealing primer and template, before their addition to a reaction mixture including enzyme, detergent, and nucleoside triphosphates, was employed at the time the invention was made. As already discussed, the courts have held that "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). The rejections were not made solely based on the teachings of Olsen, Soderlund or Barnes, but employed the use of common scientific knowledge and motivation provided in the prior art when the instant invention was made.

With regard to the citation of In re Geisler, In re Geisler, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997), while the court held that "A prima facie case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention", the court found that the reference did not teach away. MPEP 2144.05 states "(Applicant argued that the prior art taught away from use of a protective layer for a reflective article having a thickness within the claimed range of "50 to 100 Angstroms."

Art Unit: 1634

Specifically, a patent to Zehender, which was relied upon to reject applicant's claim, included a statement that the thickness of the protective layer "should be not less than about [100

Angstroms]." The court held that the patent did not teach away from the claimed invention.

"Zehender suggests that there are benefits to be derived from keeping the protective layer as thin as possible, consistent with achieving adequate protection. A thinner coating reduces light

absorption and minimizes manufacturing time and expense. Thus, while Zehender expresses a

preference for a thicker protective layer of 200-300 Angstroms, at the same time it provides the

motivation for one of ordinary skill in the art to focus on thickness levels at the bottom of

Zehender's suitable' range- about 100 Angstroms- and to explore thickness levels below that

range. The statement in Zehender that [i]n general, the thickness of the protective layer should be

not less than about [100 Angstroms]' falls far short of the kind of teaching that would discourage

one of skill in the art from fabricating a protective layer of 100 Angstroms or less. [W]e are

therefore not convinced that there was a sufficient teaching away in the art to overcome [the]

strong case of obviousness' made out by Zehender.").

In the instant case, Sobol and Gelfand

and Scalice each teach the use of master mixes which only require the addition of nucleic acids

for the methods as well as mixes where the components are present at concentrations such that

no dilution occurs before contacting with nucleic acids and thus provide motivation for one of

ordinary skill in the art to focus on such attributes of compositions. Gelfand specifically teaches

that the attributes of exemplary master mixes was for "consistency and to avoid pipetting errors".

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. No claim is allowable over the cited prior art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Art Unit: 1634

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Jehanne Sitton
Primary Examiner
Art Unit 1634

1/17/06